

Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

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10 - Payment Rules for Drugs and Biologicals

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

Drugs for inpatient hospital and inpatient skilled nursing facility (SNF) beneficiaries are included in the respective prospective payment system (PPS) rates except for hemophilia clotting factors for hospital inpatients under Part A. These drugs and the codes used to bill for them are listed in Addendum B on the Centers for Medicare & Medicaid Services (CMS) Web site: <http://cms.hhs.gov/providerupdate/regs/cms1206cn2.pdf>. The Web site is updated as the list of drugs or codes change. HCPCS codes are used by hospitals and SNFs to bill for drugs that are separately billable through September 30, 2002, at which time national drug codes (NDC) are required by the Health Insurance Portability and Accountability Act (HIPAA). A separate payment may be made for hospital inpatients, who receive hemophilia clotting factors (but not SNF). See Chapter 3 for instructions on billing inpatient hospital hemophilia clotting factors.

All hospital outpatient drugs are excluded from SDP because the payment allowance for such drugs is determined by a different procedure. Most drugs furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but paid as part of the ambulatory payment classification (APC) for the service with which they are billed. Certain drugs, however, are paid separately. These include chemotherapeutic agents and the supportive and adjunctive drugs used with them, immunosuppressive drugs, orphan drugs, radiopharmaceuticals, and certain other drugs such as those given in the emergency room for heart attacks.

The classes of drugs required to have “pass through” payments made under the Balanced Budget Refinement Act of 1999 (BBRA) have coinsurance amounts that can be less than 20 percent of the Average Wholesale Price (AWP). This is because pass-through amounts, by law, are not subject to coinsurance. The CMS considers the amount of the payment rate that exceeds the estimated acquisition cost of the drug to be the pass-through amount. Thus, the coinsurance is based on a portion of the payment rate, not the full payment rate.

Drugs are billed in multiples of the dosage specified in the HCPCS/NDC. If the dosage given is not a multiple of the Health Insurance Common Procedure Coding System (HCPCS) code, the provider rounds to the next highest units in the HCPCS description for the code.

If the full dosage provided is less than the dosage for the code specifying the minimum dosage for the drug, the provider reports the code for the minimum dosage amount.

The OPPS PRICER includes a table of drugs and prices and provides the intermediary (FI) with the appropriate prices.

Section 90 relates specifically to billing for hospital outpatients. The remainder of this chapter relates to procedures for pricing and paying DME recipients, and to beneficiaries who receive drugs under special benefits such as pneumococcal, flu and hepatitis vaccines; clotting factors, immunosuppressive therapy, self administered cancer and anti emetic drugs, and drugs incident to physicians services.

Drugs and biologicals not paid on cost or prospective payment basis have been paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., Red Book, Price Alert, etc.). Examples of drugs that have been paid on this basis include but are not limited to drugs furnished incident to a physician's service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors. The Medicare Prescription Drug, Improvement, and Modernization Act (MPDIMA) of 2003 changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. Beginning January 1, 2004, through December 31, 2004, such drugs or biologicals are paid based on various standards specified in the statute, although the default standard is 85 percent of AWP. See §20, below for a full discussion of the basis for drugs in this category during 2004.

For services furnished on or after January 1, 2005, the payment allowance limit for drugs and biologicals is based on the Average Sales Price (ASP). This pricing file will be provided to contractors by CMS.

20 - Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis

(Rev. 131, 03-26-04)

AB-02-075, AB-02-174, PRM 2711.2 B.2, B3-5202, R1799B3

Prior to January 1, 2004, drugs and biologicals not paid on cost or prospective payment are paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., Red Book, Price Alert, etc.). Examples of drugs that are paid on this basis include, but are not limited to, drugs furnished incident to a physician's service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. For January 1, 2004, through December 31, 2004, such drugs or biologicals are paid as described below:

- The payment limits for blood clotting factors will be 95 percent of the AWP.
- The payment limits for new drugs or biologicals will be 95 percent of the AWP. A new drug is defined as an unlisted drug (not currently covered by a HCPCS code) that was FDA approved subsequent to April 1, 2003. A drug would not be considered new if: the brand or manufacturer of the drug changed; a new formulation of the vial size is developed; or the drug received a new indication.
- The payment limits for pneumococcal and hepatitis B drugs and biologicals will be 95 percent of the AWP.
- The payment limits for certain drugs studied by the OIG and GAO are based on the percentages of the April 1, 2003 AWP's specified on Table 1 below.

- The payment limits for infusion drugs furnished through an item of implanted durable medical equipment on or after January 1, 2004, will be 95 percent of the October 1, 2003 AWP.
- Drugs and biologicals not described above are paid at 85 percent of the April 1, 2003 AWP.

Payment limits determined under this instruction shall not be updated during 2004.

Table 1: Percentages of April 1, 2003 AWP for Selected Drugs

HCPCS	Applicable Percentage
J0640	80
J1100	86
J1260	80
J1440	81
J1441	81
J1561/J1563	80
J1626	80
J1642	80
J2405	87
J2430	85
J2820	80
J7320	82
J7517	86
J7608	80
J7619	80
J7631	80
J7644	80
J8520/J8521*	90

J9000	80
J9045	81
J9170	80
J9201	80
J9202	80
J9206	80
J9217	81
J9265	81
J9310	81
J9350	84
J9390	81
Q0136	87

* Use the following NDC numbers when processing claims:

00004-1100-20 150 mg

00004-1100-51 150 mg

00004-1101-16 500mg

00004-1101-50 500mg

20.1 – MMA Drug Pricing – Average Sales Price

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

In general, CMS establishes a single, national payment limit for FI and carrier payment for each Medicare-covered drug whose payment is determined based on the methodology described above.

The CMS provides **an ASP** file to each carrier and FI for pricing drugs. For services furnished during 2004, the carrier shall develop payment limits using the above methodology only when CMS does not supply a payment limit for the drug. Each FI and carrier must accept the **ASP** files made available by CMS for pricing bills/claims for any drug identified on the process files.

Beginning January 1, 2005, the payment limit for Part B drugs and biologicals will be based on the Average Sales Price (ASP). Drugs will be paid based on the lower of the submitted charge or the ASP.

These drugs continue to be priced based on date of service. These drug payment limits will be distributed to contractors by CMS. CMS will update and provide this file quarterly. Carriers/DMERCs/SADMERC shall develop payment limits when CMS does not supply a payment limit for the drug on the file.

20.1.1 – Online Pricing Files for Average Sales Price

(Rev. 509, Issued: 03-18-05; Effective: 07-01-05; Implementation: 07-05-05)

Beginning July 1, 2005, the standard for the number of online pricing files maintained by DMERCs for determining the applicable allowed amount for paying drug claims is eight fee screens/pricing files for Part B drugs billed to DMERCs for payment on a fee-for-service basis.

20.2 - Single Drug Pricer (SDP)

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

Effective January 1, 2003, contractors pay drug claims on the basis of the prices shown on the SDP files, if present.

On a quarterly basis, CMS furnishes three SDP files to all FIs, carriers, and ROs except regional home health intermediaries (RHHIs) and durable medical equipment regional carriers (DMERCs), as follows:

1. “HCPCS” Drug Pricing File

- a. CMS furnishes a SDP file that contains drugs identified by a code established by the Health Care Procedure Code System (HCPCS). This HCPCS drug-pricing file (HDPF) contains:
 - Every HCPCS drug code for every drug for which claims are submitted to

- local carriers (excluding DMERCs);
 - With respect to each such HCPCS code, the unit of measure by which such HCPCS code is defined;
 - With respect to each HCPCS code and unit of measure, the Medicare allowed amount;
 - With respect to each HCPCS code for which the price has changed from the price determined in the previous quarter, an indication as to whether the new price is higher or lower than the price determined in the prior quarter;
 - With respect to each new HCPCS code, an indicator to that effect; and
 - with respect to each deleted HCPCS code, an indicator to that effect.
- b. The filename convention is as follows: (1) “hdpf” in the first 4 positions (2) positions 5-8 correspond to the year and quarter for which the file is applicable (e.g., hdpf0301.xls).
- c. An HDPF will be made available approximately 30 days before the beginning of each calendar quarter, i.e., on or about each February 1, May 1, August 1, and November 1.

2. “Not otherwise classified” (NOC) Drug Pricing File

- a. CMS furnishes a NOC SDP file for drugs “not otherwise classified.” This NOC drug pricing file (NDPF) contains:
- With respect to every drug NOC under the HCPCS for which claims are submitted to local carriers (excluding DMERCs), the NDC code and drug name;
 - With respect to each such NDC code, the unit of measure by which such drug is covered;
 - With respect to each NOC drug, the Medicare allowed amount;
 - With respect to each NOC drug for which the price has changed from the price determined in the previous quarter, an indication as to whether the new price is higher or lower than the price determined in the prior quarter;
 - With respect to each new NOC drug, an indicator to that effect; and
 - With respect to each deleted NOC drug, an indicator to that effect.
- b. The filename convention is as follows: (1) “ndpf” in the first 4 positions (2) positions 5-8 correspond to the year and quarter for which the file is applicable (e.g., the initial NOC file’s filename was “ndpf0301.xls”).
- c. The CMS makes a revised NDPF available approximately 30 days before the beginning of each calendar quarter, i.e., on or about each February 1, May 1, August 1, and November 1.

NOTE TO FIs: The NOC file does not necessarily contain all NOC drugs. FIs must

contact local carriers to determine if there are other drugs the carrier has priced separately and request the prices for those drugs as needed.

3. The CMS furnishes a pricing documentation file (PDF) that contains only new drugs and biologicals for which a Medicare price has been established since the previous quarter:

- a. The data in the drug pricing file, i.e., each HCPCS code and its Medicare allowed amount;
- b. With respect to each HCPCS drug code, every product, as identified by its NDC code, that contains the same active ingredient as specified in the definition of the HCPCS code;
- c. With respect to those NDC codes used to determine the Medicare-allowed amount, an indicator to that effect;
- d. With respect to each such NDC, the price or prices used to determine the average wholesale price (AWP) of the product;
- e. With respect to each such price, an identification of the source(s) of the price; and
- f. With respect to each such source, the date, edition, and other information necessary and sufficient to enable CMS to verify the price.

Except as specifically noted, each FI and carrier will:

- Upon receiving the quarterly update files, execute its normal update process using the SDP files. If necessary, the contractor shall process manually to implement SDP file prices effective with the beginning of the following quarter.
- Compare the prices it paid previously with the prices shown on the prior SDP file; taking note of the unit pricing quantity shown on the applicable SDP file and comparing it to the unit pricing quantity to ensure that any apparent price changes are real.
 - Carriers must notify physicians of price changes.
 - FIs must notify ESRD facilities (with respect to ESRD drugs not included in the composite rate) and hospitals (with respect to clotting factors) of price changes to the extent and in the manner you have done previously.
- Advise the RO of any price on a SDP file it believes is not correct.
- Not substitute its price for the price shown on an SDP file unless authorized to do so by a joint memorandum from CMS.
- If updated prices, in whole or in part, are not made available on a timely basis, use the prices from the prior quarter's SDP files to the extent necessary.
- Carriers continue to price drugs as outlined in §20.2 with respect to any drug that is not listed on the SDP files and with respect to any compounded drug that is not

identified by a single NDC.

- Report to the RO, on or before March 1 of each year, whether any drugs are being priced separately, including but not limited to NOC drugs. If one or more drugs are being priced separately, then the name of the drug, its NDC, the price determined, and the source used to price drug must also be included in the report.
- Carriers and FIs: Publish current SDP prices on their Web site immediately upon receipt of the file from CMS.
- FIs: As needed on a quarterly basis and within seven days of receipt of the SDP files, request, from carriers, prices of drugs that carriers may price separately.
 - Carriers: Upon request, on a quarterly basis and within seven days of any such request, furnish to FIs within jurisdiction, free of charge, the subset of files, which includes drugs that are priced separately.
- FIs and Carriers: Respond to questions about price changes and the implementation of AWP pricing as done previously. Contractors respond to questions about the SDP on the basis of these instructions. Questions that cannot be answered should be referred to the RO.
- The MCS Carrier shared systems shall maintain eight fee screens/pricing files (a current period and seven prior periods) for Part B “incident to” drugs billed to carriers for payment on a fee-for-service basis. (**NOTE:** VIPS is waived and will continue to carry 5 pricing periods)
- Since they post the updated SDP file to their Web site upon receipt from CMS, carriers are waived from the requirement to give 30 days advance notice for fee schedule changes with respect to drugs.
- SDP does not preclude the use of inherent reasonableness or the establishment of local medical review policies, including the use of a least costly alternative.
 - If a least costly alternative is determined and a process for the least costly alternative exists on the SDP, the SDP price for the least costly alternative must be used.
- Medicare coverage determinations are independent of the SDP. The presence or absence of a price for a particular drug in the SDP is irrelevant to Medicare coverage determinations.
- EPO=Q codes are included in the SDP, applicable to physician claims. The statutory limit for EPO applies to nonphysician claims.
- “Unit Measurement” means the amount of whatever measurement is used in the

code description (e.g., milligrams (mg)).

ROs:

1. Advise carriers concerning the implementation of the SDP.
2. Respond to questions about drug price changes.
3. Respond to questions about the implementation of the AWP pricing methodology.
4. Respond to questions about the SDP on the basis of these instructions.
5. Refer any questions that cannot be answered to central office (CO) per item 6, below.
6. Advise CO of matters that require CO attention.

**20.3 – Calculation of the Payment Allowance Limit for DMERC Drugs
(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)**

Payments for drugs billed to the DMERCs will be based on the implementation of the MPDIMA, beginning January 1, 2004, and will be paid at 85 percent of the AWP for HCPCS payment amounts based on the April 1, 2003 fee schedule. Exceptions to this calculation are as follows:

The payment limits for infusion drugs furnished through an item of durable medical equipment on or after January 1, 2004, will be 95 percent of the October 1, 2003 AWP.

- The payment limits for new drugs or biologicals will be 95 percent of the AWP. A new drug is defined as an unlisted drug (not currently covered by a HCPCS code) that was FDA approved subsequent to April 1, 2003. A drug would not be considered new if: The brand or manufacturer of the drug changed; a new formulation of the vial size is developed ; or the drug received a new indication.

The payment limits for certain drugs studied by the OIG and GAO are based on the percentages of the April 1, 2003 AWP's specified on Table 1 in §20 .

Payment limits determined under this instruction shall not be updated during 2004.

20.4 - Calculation of the AWP

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

See Business Requirements and Excel Spreadsheets at
http://www.medicaid.com/manuals/pm_trans/R54CP.pdf
http://www.medicaid.com/manuals/pm_trans/R55CP.pdf

Carriers must ensure that if any NDCs are added or deleted, the formulae are applied appropriately.

A separate AWP is calculated for each drug as defined by a HCPCS code. Within each HCPCS code there may be a single source or there may be many sources, or there may be no source.

- For a single-source drug or biological, the AWP equals the AWP of the single product.
- For a multi-source drug or biological, the AWP is equal to the lesser of;
 - The median AWP of all generic forms of the drug or biological; or
 - The lowest brand name product AWP.

A “brand name” product is defined as a product that is marketed under a labeled name that is other than the generic chemical name for the drug or biological.

NOTE: Repackagers make the status of the drug a multi-source.

After determining the AWP, carriers multiply it by 0.85 or 0.95, or other percentage, as applicable, and round to the nearest penny. This is the drug payment allowance limit. Carriers round it in accordance with standard rounding procedure. Part B coinsurance and deductible requirements apply.

In applying this procedure, carriers use the package sizes that are most commonly used for the most frequently administered dosage of the drug.

Intermediaries get drug prices from the carrier for drugs not listed on the Single Drug Pricer.

20.5 - Detailed Procedures for Determining AWP and the Drug Payment Allowance Limits

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

20.5.1 - Background

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

Payment for drugs and biologicals under Medicare is determined by a standard methodology. Law and regulations require that a drug payment allowance limit be used as described in §20.1. (See 42 CFR 405.517 and MPDIMA, Section 303(b))

The earliest drug payment allowance limit effective in 2004 will not be subsequently updated during 2004. When limits are initially established, carriers inform FIs and the provider community as described in paragraph §30 below.

20.5.2 - Review of Sources for Medicare Covered Drugs and Biologicals

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

Carriers check updates for Medicare covered services or procedures for new codes or code description changes before updating files.

For new codes, the Carrier Medical Staff determines coverage in accordance with the coverage rules in Chapter 15 of the Medicare Benefit Policy Manual.

Carriers refer to common sources for drug pricing information. Examples are the various Redbook products, “Drug Facts and Comparisons,” the FDA publication Approved Drug Products with Therapeutic Equivalence (the Orange Book), or the “Hospital Formulary Pricing Guide” by MediSpan, Inc. If a price cannot be located in the available sources, they contact the manufacturer of the drug.

If a code has a description change, carriers adjust formulas to account for any changes in the strength or dosage of the drug. For example, if a code is listed as 50 mg, and changed to 100 mg, the drug payment allowance limit is adjusted to compensate for the difference in the dosage.

20.5 3 - Use of Generics

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

Carriers identify the generic name of the drug from the code description. They always rely on the CMS HCPCS tape file or an official HCPCS publication.

Carriers locate generic sources in the Drug Topics Redbook or other source based on the HCPCS description of the drug. They use entries that match the strength of the drug described by the HCPCS code, e.g., 50 mg, 100 mg, etc.

To determine if a drug is generic or brand, carriers compare the name of the drug in the HCPCS code (generic) with the name of the drug being identified. If they are the same, the drug is generic. If they are different, the drug is a brand. For example, the description for J3360 is injection, diazepam, up to 5 mg. Diazepam is the generic name. The HCPCS code for Valium is listed as J3360. Valium is a brand name.

If there is a question as to whether a drug is brand or generic, carriers consult the PDR Generics, or telephone the drug company.

20.5. 4 - Find the Strength and Dosage

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

Carriers use ampules, single dose and multiple dose vials and repacks to compare the strength and dosage. If multiple dose vials are used, carriers must determine how they are used, based on the strength indicator compared with the HCPCS code description (i.e., if the strength on the vial matches the HCPCS description, multi-dose vials should be used).

Carriers must determine which of the following conditions are true before pricing the drug:

1. The strength and dosage of the drugs in the price source match the HCPCS code and description.

Carriers calculate allowable reimbursements for drugs using “all” the NDCs for a given active drug ingredient and calculate a unit price that is associated with the HCPCS descriptor. If, for example, the HCPCS code descriptor specifies 50 ml and there is a 50 ml size shown in the Redbook or other source material, they may use only the 50 ml size (and not use 10-5 ml vials) or may use all products that meet the strength based on strength and volume of the drug. In the latter case price per unit is calculated and then converted to the HCPCS units definition.

2. The strength and dosage from the HCPCS code description are not found in the price source.

Carriers use the closest dosage to the HCPCS definition without exceeding the dosage.

3. The strength and dosage in the price source do not include a generic form but do include a brand form.

Carriers use the lowest brand price.

20.5.5 - Restrictions

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

To determine AWP and Payment Allowance Limits, carriers:

- Exclude special sized packaging, e.g. Institutional Use.
- Do not use flip top vial, carpu-ject, tubes, cartridge, rapi-ject, lure lock syringe, blunt point abu-ject, rapi-ject, leurlock, advantage, min-i-jet, unless it is the only source available. These items are considered convenience and tend to inflate the price.
- Do not use drugs marked preservative free, sulfite free, piggy back, or sterile unless the HCPCS description specifies otherwise.
- Do not use drugs with an Orange Book Code (OBC) other than “A” if more than one source exists. This restriction applies to SADMERC only (reference CMS Memorandum PUB 60 AB.94-2, 60 dated March 1994).

20.5.6 - Inherent Reasonableness for Drugs and Biologicals

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

Section 4316 of the Balanced Budget Act of 1997 permits Medicare carriers to establish realistic and equitable payment amounts for drugs when the existing payment amounts are inherently unreasonable because they are either grossly excessive or deficient. Refer to chapter 23, for a complete description of Inherent Reasonableness rules.

Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to the following:

1. Payment amounts for drugs or biologicals are grossly higher or lower than acquisition or production costs for the category of items or services.
2. There have been increases in payment amounts that cannot be explained by inflation or technology.

In some instances, the calculation of the AWP may lead to a payment limit that is not reasonable for the purpose of paying for drugs and biologicals. Carriers can apply the principal of inherent reasonableness in selecting the drugs to be included in the calculation. For instance in situations where there are some drugs in a HCPCS grouping that are significantly more expensive due to having preservatives added, there is no effect on the quality of the drug whether or not there are preservatives. Therefore, leave the drugs with preservatives out of the calculation.

While carriers and FIs may determine under their inherent reasonableness authority that a greater than 15 percent increase or decrease in payment amounts is warranted, they may not increase or decrease the payment amounts for any item by greater than 15 percent in any given year. However, a contractor may determine that a 25 percent reduction is warranted, and accomplish the adjustment over 2 years, e.g., 15 percent applied the first year, and 10 percent applied the following year.

In addition, a contractor must inform CMS of any inherent reasonableness determinations. The CMS will then acknowledge receipt of the notification. The payment adjustment may not take effect until the contractor has notified CMS and received CMS's acknowledgment of the notification.

Notification should be sent to CMS Central Office (CO) at the following address:

Centers for Medicare & Medicaid Services
Center for Medicare Management
Provider Billing Group
C4-10-07
7500 Security Boulevard
Baltimore, Maryland 21244-1850

20.5.7 – Injection Services

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

Where the sole purpose of an office visit was for the patient to receive an injection, payment may be made only for the injection service (if it is covered). Conversely, injection services (codes 90782, 90783, 90784, 90788, and 90799) included in the Medicare Physician Fee Schedule (MPFS) are not paid for separately, if the physician is paid for any other physician fee schedule service furnished at the same time. Pay separately for those injection services only if no other physician fee schedule service is being paid. However, pay separately for cancer chemotherapy injections (CPT codes 96400-96549) in addition to the visit furnished on the same day. In either case, the drug is separately payable. All injection claims must include the specific name of the drug and dosage. Identification of the drug enables you to pay for the services.

20.5.8 – Injections Furnished to ESRD Beneficiaries

(Rev. 397, Issued: 12-16-05, Effective: 01-01-05, Implementation: 01-03-05)

When an ESRD beneficiary is given a renal related injection outside the ESRD facility or provider-setting, it should be administered by the beneficiary's monthly capitation payment (MCP) physician or his/her staff as "incident to" such physician's services.

There is no additional allowance for the physician or his staff, e.g., an office nurse. This is because payment for the administration of a renal-related injection to a dialysis patient is included in the physicians' monthly capitation payment (MCP).

The regulations governing Medicare payment for physicians' ESRD services ([42 CFR 405.542](#)) require that all physicians' outpatient ESRD-related services except declogging shunts be paid under the MCP. If a physician, other than the patient's MCP physician, administers a renal-related injection, the other physician must look to the MCP physician for compensation for the services.

Although an additional allowance for the administration of a renal-related injection to a dialysis patient may not be made, the patient's MCP physician or a physician other than the MCP physician may submit claims and be paid for the drug itself as well as supplies, e.g., needles and syringes, used to administer the drug.

EXAMPLE: Dr. Jones is Mr. White's MCP physician. Dr. Jones is unable to furnish the regular EPO injections his patient needs three times a week. It is Dr. Jones' responsibility to compensate the physician who administers the injections. The administering physician submits claims for the injectable and necessary supplies. In this case, the carrier makes a reasonable monthly allowance, e.g., \$3 for the cost of supplies (i.e., syringes and needles).

30 - Carrier Distribution of Limit Amounts

(Rev. 1, 10-01-03)

B3-5202.1

The FIs get drug prices from the carrier for drugs not listed on the SDP.

Carriers prepare a list of the drug payment allowance limits updates (or new file depending upon local requirements) to the claims system.

Carriers distribute, free of charge, the updated limits in an agreed upon format directly to the FIs in their jurisdiction.

Carriers should contact each FI to determine the preferred method of transmission. Carriers are to send this information to all FIs they routinely deal with. If this method of obtaining payment allowance updates does not work for any FI, the carrier must contact the appropriate RO office.

40 - Discarded Drugs and Biologicals

(Rev. 1, 10-01-03)

AB-02-075, PRM 2711.2 B. 2

The CMS encourages physicians to schedule patients in such a way that they can use drugs most efficiently. However, if a physician must discard the remainder of a vial or other package after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered.

NOTE: The coverage of discarded drugs applies only to single use vials. Multi-use vials are not subject to payment for discarded amounts of drug.

EXAMPLE 1:

A physician schedules three Medicare patients to receive Botulinum Toxin Type A on the same day within the designated shelf life of the product. Currently, Botox is available only in a 100-unit size. Once Botox is reconstituted in the physician's office, it has a shelf life of only four hours. Often, a patient receives less than a 100 unit dose. The physician administers 30 units to each patient. The remaining 10 units are billed to Medicare on the account of the last patient. Therefore, 30 units are billed on behalf of the first patient seen and 30 units are billed on behalf of the second patient seen. Forty units are billed on behalf of the last patient seen because the physician had to discard 10 units at that point.

EXAMPLE 2:

A physician must administer 15 units of Botulinum Toxin Type A to a Medicare patient, and it is not practical to schedule another patient who requires Botulinum Toxin. For example, the physician has only one patient who requires Botulinum Toxin, or when the physician sees the patient for the first time and did not know the patient's condition. The physician bills for 100 units on behalf of the patient and Medicare pays for 100 units.

50 - Assignment Required for Drugs and Biologicals

(Rev. 1, 10-01-03)

PM B-01-15, B3-5247

A. Local Carriers

Under §114 of the Benefits Improvement Act of 2000, effective for claims with dates of service on or after February 1, 2001, payment for any drug or biological covered under Part B of Medicare may be made only on an assignment-related basis. Therefore, no charge or bill may be rendered to anyone for these drugs and biologicals for any amount except for any applicable unmet Medicare Part B deductible and coinsurance amounts. All entities (including physicians, nonphysicians practitioners, pharmacies and suppliers) that bill Medicare for drugs and biologicals must take assignment on all claims for drugs and biologicals furnished to any beneficiary enrolled in Medicare Part B. Contractors apply this policy to all items paid based on the lower of the actual charge on the claim or 95 percent of the AWP. See §§20 for a description of the AWP.

Mandatory assignment does not apply to HCPCS code E0590, which represents the dispensing fee for nebulizer drugs.

Carriers process all claims for drugs and biologicals with a date of service on or after February 1, 2001, as though the physician or nonphysician practitioner had taken assignment. If only drugs and biologicals are billed on the claim, and the claim was submitted as unassigned, contractors change the claim to assigned and process as an assigned claim. If a physician or nonphysician practitioner submits an unassigned claim that contains both codes for drugs or biologicals and codes for other services, carriers split the claim into two claims. The first claim will be an unassigned claim for services other than drugs or biologicals, and the second will be an assigned claim for drugs or biologicals furnished on or after February 1, 2001. The following messages apply when a carrier has changed the claim to assigned status (regardless of whether the contractor had to split the claim):

- Remittance advice remark code N71, "Your unassigned claim for a drug or biological, clinical diagnostic laboratory services or ambulance service was processed as an assigned claim. You are required by law to accept assignment for these types of claims."
- MSN 16.50 English, "The doctor or supplier may not bill more than the Medicare approved amount," **or** MSN 16.50 Spanish, "El doctor o suplidor no podrá facturar más que la cantidad aprobada por Medicare."
- Remark Code MA 72, "The beneficiary overpaid you for these assigned services. You must issue the beneficiary a refund within 30 days for the difference between

his/her payment to you and the total amount shown as patient responsibility and as paid to the beneficiary on this notice.”

Additional appropriate message for physicians, suppliers, and beneficiaries should be added as necessary.

B. DMERCs

Under §114 of BIPA, DMEPOS suppliers must accept assignment on all claims for drugs and biologicals that they bill to the DMERCs. A supplier may not render a charge or bill to anyone for these drugs and biologicals for any amount other than the Medicare Part B deductible and coinsurance amounts.

Mandatory assignment does not apply to HCPCS code E0590, which represents the dispensing fee for nebulizer drugs.

The DMERCs must inform suppliers on their Web sites and in their next bulletins that they must accept assignment on claims for drugs and biologicals furnished on or after February 1, 2001.

The DMERCs must deny any claims a beneficiary submits for drugs and biologicals with dates of service on or after February 1, 2001. The DMERCs must notify beneficiaries that suppliers must accept assignment on claims for drugs and biologicals, and therefore, the beneficiaries may not submit claims for drugs and biologicals. When denying beneficiary-submitted claims, DMERCs use the following Medicare Summary Notice (MSN) messages:

MSN 16.6 (English): “This item or service cannot be paid unless the provider accepts assignment.”

MSN 16.6 (Spanish): “Este artículo o servicio no se pagará a menos de que el proveedor acepte asignación.”

MSN 16.7 (English): “Your provider must complete and submit your claim.”

MSN 16.7 (Spanish): “Su proveedor debe completar y someter su reclamación.”

MSN 16.34 (English): “You should not be billed for this service. You do not have to pay this amount.”

MSN 16.34 (Spanish): “Usted no debería ser facturado por este servicio. Usted no tiene que pagar esta cantidad.”

MSN 16.36 (English): “If you have already paid it, you are entitled to a refund from this provider.”

MSN 16.36 (Spanish): “Si usted ya lo ha pagado, tiene derecho a un reembolso de su proveedor.”

If a supplier submits an unassigned claim with a date of service on or after February 1, 2001, to the DMERC for a drug or biological, the DMERC must process the claim as though the supplier accepted assignment. It is possible that a supplier may bill drugs and

other items on the same claim, which would result in a claim with some assigned and some nonassigned items.

In the event that a supplier bills an unassigned claim to a DMERC that contains both codes for drugs or biologicals and codes for other items, the DMERCs must replicate the claim. This will result in two claims in the DMERC system: an unassigned claim for items other than drugs or biologicals, and an assigned claim for drugs and biologicals furnished on or after February 1, 2001. When a DMERC changes an unassigned drug claim to an assigned claim, it must use the following messages on the supplier remittance advice (RA):

Remark code MA72: “The beneficiary overpaid you for these assigned services. You must issue the beneficiary a refund within 30 days for the difference between his/her payment to you and the total of the amount shown as patient responsibility and as paid to the beneficiary on this notice.” (VMS shared system maintainer must use remark code MA72 on the claim level on the remittance advice for drugs and biologicals when the incoming claim indicated that the patient had already paid for the billed services.)

Remark code N71: “Your unassigned claim for a drug or biological was processed as an assigned claim. The law requires that you must take assignment on all claims for drugs and biologicals.”

The VMS Shared System Maintainer must hard-code RA message MA72 and RA message N71 into its system.

Suppliers that bill the DMERCs for drugs for use with DMEPOS must have a pharmacy license to dispense drugs. When a DMERC denies a claim for a drug because the National Supplier Clearing House (NSC) records do not show that the supplier has a pharmacy license, the DMERC must also deny any equipment, accessories, and supplies related to the drug, when the supplier bills the drug on the same claim as the equipment. (Suppliers should bill drugs for use with DMEPOS on the same claim as the equipment itself, if they are also providing and billing for the equipment.) In situations when a supplier bills unassigned drugs and equipment, accessories, or supplies on the same claim, the DMERC and VMS Shared System Maintainer must ensure that they apply nonlicensed pharmacy equipment, accessory and supply edits and denials before they replicate the claim. Even if the system denies a line due to the nonlicensed pharmacy edit prior to replicating the claim, the system must still replicate any unassigned claims for drugs and biologicals and change the assignment indicator. DMERCs use the following messages to suppliers, as appropriate:

RA Remark code MA72: “The beneficiary overpaid you for these assigned services. You must issue the beneficiary a refund within 30 days for the difference between his/her payment to you and the total of the amount shown as patient responsibility and as paid to the beneficiary on this notice.” (VMS shared system maintainer must use remark code MA72 on the claim level on the remittance advice for drugs and biologicals when the incoming claim indicated that the patient had already paid for the billed services.)

RA Remark code N71: “Your unassigned claim for a drug or biological was processed as an assigned claim. The law requires that you must take assignment on all claims for drugs and biologicals.”

RA Adjustment reason code B6: “This service/procedure is denied/reduced when performed/billed by this type of provider, by this type of provider in this type of facility, or by a provider of this specialty.”

RA Adjustment reason code #107: “Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.”

RA Remark code M143: “We have no record that you are licensed to dispense drugs by the state in which you are located.”

The DMERCs must work together to create and maintain a list of HCPCS drug codes that suppliers must bill on an assigned basis. This will enable VMS shared system maintainer and the DMERCs to implement the necessary edits in their systems. Finally, the four DMERCs must work together to create a list of drug and equipment codes to which the nonlicensed pharmacy edit would apply in this situation. For this second list, the DMERCs need add only drugs that are used with equipment, and the equipment, and related supplies and accessories, that use those drugs, as opposed to all drugs that are subjected to the licensure edit. The DMERCs must share these lists with VMS shared system maintainer and CMS Central Office.

60 – DMEPOS Suppliers Require a License to Dispense Drugs

(Rev. 1, 10-01-03)

PM B-01-02

Regulations at 42 CFR 424.57(b)(4) (supplier standards) state that a “supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs. (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician’s license.)”

Therefore, suppliers may not bill the durable medical equipment regional carriers (DMERCs) for any Medicare-covered drugs unless they have a State license to dispense the drugs, regardless of whether or not the drugs require a prescription. Similarly, a physician may not dispense Medicare-covered prescription or nonprescription drugs unless he or she is authorized by the State to dispense such drugs as part of his or her physician’s license.

The DMERCs must deny claims for prescription drugs, and related equipment when billed on the same claim, if the National Supplier Clearinghouse’s (NSC) records show the supplier was not licensed to dispense the drug on the DOS (date of service).

In effect, for DOS on or after December 11, 2000, the DMERCs must deny claims for all Medicare- covered drugs dispensed by a supplier or physician who is not licensed to dispense the drug. If the DMERCs feel that it is necessary, they may coordinate to develop a list of drugs and related equipment that should be subjected to the licensure edit.

Note that these provisions do not apply to EPO. Method I beneficiaries must obtain their EPO through their dialysis facilities, and Method II beneficiaries must receive EPO from the same supplier that provides all their other dialysis supplies.

60.1 - Prescription Drugs Billed by Suppliers Not Licensed to Dispense Them

(Rev. 1, 10-01-03)

B3-4118

Medicare does not cover a drug used as a supply with DME or a prosthetic device if the drug is dispensed by an entity that is not licensed to dispense the drug. The drug is not considered to be reasonable and necessary because CMS cannot be assured of its safety and effectiveness unless it is dispensed by an entity that has a State license that qualifies it to dispense the drug. The equipment used with the drugs dispensed by a nonlicensed entity is also considered to be not reasonable and necessary because of the related safety and efficacy concerns. Physicians are considered to have been “deemed” the right to dispense prescription drugs, and therefore do not require a pharmacy license.

The DMERCs should deny claims for a prescription drug (and related equipment when billed on the same claim as the drug) when the National Supplier Clearinghouse’s (NSC’s) files show the supplier is or was not licensed to dispense the drugs on the date of service (DOS).

An exception to this general policy is oxygen claims.

Messages for Assigned Claims:

“Medicare cannot pay for this drug/equipment because our records do not show your supplier is licensed to dispense prescription drugs, and, therefore, cannot assure the safety and effectiveness of the drug/equipment. You are not financially liable for any amount for this drug/equipment unless your supplier gave you a written notice in advance that Medicare would not pay for it and you agreed to pay.” (MSN #8.50.)

Remittance for Drugs: “This service/procedure is denied/reduced when performed/billed by this type of provider, in this type of facility, or by a provider of this specialty.” (Remittance advice code B6, with group code CO - the provider may not bill the beneficiary.)

Additionally, the following remark code should appear on the remittance notices: Remark code M143: “We have no record that you are licensed to dispense drugs by the State in which you are located.”

Messages for Nonassigned Claims:

MSN: “This item or service is not covered when performed or ordered by this provider.” (MSN #12.18)

Appeals should be addressed according to the instructions in Chapter 29.

70 - Claims Processing Requirements - General

(Rev. 1, 10-01-03)

No cross reference - CMS Staff developed

Carriers are billed with the Form CMS-1500 data set and FIs with the Form CMS-1450 data set (paper or approved EDI data set).

See chapters 25 and 26 for detailed claims processing requirements, including forms, data elements, and formats; and chapters 21 and 22 for MSN and remittance record requirements.

In addition to requirements applicable to all claims the following apply to drug claims.

- On claims to FIs the drug is identified by the appropriate HCPCS code for the drug administered and billed under revenue code 0636 unless specific instruction states otherwise;
- On claims to carriers the drug is identified by HCPCS code;
- All drugs, including Prodrugs, are reported to DMERCS by National Drug Code (see §80.1.2);
- Where HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 mg., and 200 mg are provided, units are shown as 4;
- Where the NDC is required units are entered in multiples of the units shown in the NDC label description. For example, if the description for the code is 50 mg., and 200 mg are provided, units are shown as 4;
- If the units provided exceeds the size of the units field, e.g., requires over three characters to report, repeat the HCPCS or NDC code on multiple lines until all units can be reported;
- Covered administration codes for injections may be billed to the carrier and FI in addition to billing for the drug. The drug maximum payment allowance is for the drug alone. However, if payment is under a PPS, such as OPPS, the injection would be included in the APC rate.

See §10 for a description of drug payment rules.

70.1 – Billing Drugs Electronically - NCPDP

(Rev. 867, Issued: 02-17-06, Effective: 04-01-06, Implementation: 04-03-06)

The National Council for Prescription Drug Programs (NCPDP) Telecommunications Standard Version 5.1 and Batch Standard 1.1 is the HIPAA standard for electronic retail pharmacy drug claims and coordination of benefits (COB).

The CMS has issued a companion document for NCPDP in PM-B-03-041

DMERCs that process retail pharmacy drug transactions require their retail pharmacy claimants to use this standard. Retail pharmacies must use the American National Standards Institute (ANSI) Accredited Standards Committee (ASC) ANSI X12N 837P

HIPAA version Health Care Claim format to submit claims other than retail pharmacy claims to the DMERCs.

DMERCs and VIPS shall accommodate quarterly and monthly NDC crosswalk updates as needed. DMERCs shall reject NDC codes that have been deactivated/end dated.

A - Requirements for Implementing the NCPDP Standard

Retail pharmacies will be identified by a value of A5 in the specialty code as received by the National Supplier Clearinghouse. Only DMERC suppliers with an A5 specialty code may use the NCPDP standard. The DMERCs, their EDI submitters, and their other trading partners are required to transmit the NDCs in the NCPDP standards for identification of prescription drugs dispensed through a retail pharmacy. NDCs replace the drug HCPCS codes for retail pharmacy drug transactions billed to DMERCs via the NCPDP standards.

B - Certificate of Medical Necessity (CMN)

The CMN for Parenteral Nutrition (Form CMS-852) *is required*. The DMERC Information Form for Immunosuppressive Drugs (Form DMERC-08.02) *is not required when billing for immunosuppressive drugs with dates of service on or after April 1, 2006*. As with other electronic formats, CMN data must be submitted within the valid transaction.

For claims submitted on the Form CMS-1500, retail pharmacies will continue to supply hard copy CMNs when required.

C - NCPDP Companion Document

DMERCs are to provide the NCPDP companion document, found at: http://cms.hhs.gov/manuals/pm_trans/B03041.pdf to retail pharmacy drug claim submitters (either provider, billing agent, or clearinghouse) that will submit retail pharmacy drug claims to Medicare electronically.

70.1.1 – Reporting Modifiers in the Compound Drug Segment

(Rev. 1, 10-01-03)

B-03-057

Certain informational modifiers are required on compound ingredients. The NCPDP format does not currently support reporting modifiers in the compound segment. Therefore, the narrative portion in the prior authorization segment must be used to report these modifiers. The following must be entered in positions 001-003 of the narrative (Example, MMN or MNF). Starting at position 355, indicate the two-byte ingredient number followed by the two-position modifier:

MMN - Indicates that the Supporting documentation that follows is Medicare modifier information and CMN information or DIF information

MNA - Indicates that the Supporting documentation that follows is Medicare modifier information, CMN information or DIF information and narrative information

MFA - Indicates that the Supporting documentation that follows is Medicare modifier information, CMN information or DIF information and Facility Name and Address

MNF - Indicates that the Supporting documentation that follows is Medicare modifier information, CMN information or DIF information, narrative information and Facility Name and Address

MAC - Indicates that the Supporting documentation that follows is Medicare modifier information and Facility Name and Address

MAN - Indicates that the Supporting documentation that follows is Medicare modifier information, narrative information and Facility Name and Address

MAR - Indicates that the Supporting documentation that follows is Medicare modifier information and narrative information

70.1.2 – Coordination of Benefits (COB)

(Rev. 1, 10-01-03)

The NCPDP has approved the following use of qualifiers for reporting Medicare COB amounts:

- 07 Medicare Allowed Amount
- 08 Medicare Paid Amount
- 99 1st Occurrence – Deductible Amount
- 99 2nd Occurrence – Coinsurance Amount
- 99 3rd Occurrence – Co-Payment Amount

70.1.3 – Inbound NCPDP Claim

(Rev. 1, 10-01-03)

The DMERC needs to be able to determine whether a beneficiary has Medicaid coverage and in which state. In order to determine this, the provider must enter the two position state alpha code followed by the word “MEDICAID” in the Group ID field (Example, NYMEDICAID or FLMEDICAID). Therefore, “XXMEDICAID” must be accepted in the Group ID field (301-C1) in order to allow DMERC’s to determine that a beneficiary has Medicaid coverage in that specific state.

80 - Claims Processing for Special Drug Categories

(Rev. 1, 10-01-03)

NOTE: Preventive vaccines, influenza, pneumococcal and hepatitis B, are covered in Chapter 18 of this manual.

NOTE: The definition of Off-Label and its uses are described in the Medicare Benefit Policy Manual, Chapter 15.

80.1 - Oral Cancer Drugs

(Rev. 1, 10-01-03)

A3 3660.13, SNF 536.1

Effective January 1, 1994, oral self administered versions of covered injectable cancer drugs furnished may be paid if other coverage requirements are met. To be covered the drug must have had the same active ingredient as the injectable drug. Effective January 1, 1999, this coverage was expanded to include FDA approved Prodrugs used as anti-cancer drugs. A Prodrug may have a different chemical composition than the injectable drug but body metabolizing of the Prodrug results in the same chemical composition in the body.

80.1.1 - HCPCS Service Coding for Oral Cancer Drugs

(Rev. 1, 10-01-03)

The following codes may be used for drugs other than Prodrugs, when covered:

Generic/Chemical Name	How Supplied	HCPCS
Busulfan	2 mg/ORAL	J8510
Capecitabine	150mg/ORAL	J8520
Capecitabine	500mg/ORAL	J8521
Methotrexate	2.5 mg/ORAL	J8610
Cyclophosphamide *	25 mg/ORAL	J8530
Cyclophosphamide * (Treat 50 mg. as 2 units)	50 mg/ORAL	J8530
Etoposide	50 mg/ORAL	J8560
Melphalan	2 mg/ORAL	J8600
Prescription Drug chemotherapeutic NOC	ORAL	J8999

Each tablet or capsule is equal to one unit, except for 50 mg./ORAL of cyclophosphamide (J8530), which is shown as 2 units. The 25m and 50 mg share the same code.

NOTE: HIPAA requires that drug claims submitted to DMERCs be identified by NDC.

80.1.2 - HCPCS and NDC Reporting for Prodrugs

(Rev. 136, 04-09-04)

FI claims

For oral anti-cancer Prodrugs HCPCS code J8999 is reported with revenue code 0636.

DMERC claims

The supplier reports the NDC code on the claim. The DMERC converts the NDC code to a “WW” HCPCS code for CWF. As new “WW” codes are established for oral anti-cancer drugs they will be communicated in a Recurring Update Notification.

80.1.3 - Other Claims Processing Issues for Oral Cancer Drugs

(Rev. 1, 10-01-03)

Deductible and coinsurance apply.

A cancer diagnosis code must be reported when billing for these HCPCS codes. If there is no cancer diagnosis the claims is denied.

The number of tablets or capsules is reported as units.

80.1.4 - MSN/ANSI X12N Message Codes for Oral Cancer Drug Denials

(Rev. 1, 10-01-03)

If the claim for an oral cancer drug is denied because it was not approved by FDA, is not considered to be a medically accepted treatment for cancer, or is not the chemical equivalent of a covered injectable cancer drug (or a covered Prodrug), use the appropriate message on the MSN:

6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered. (ANSI X12 Adjustment Code 114)

6.3 - Payment cannot be made for oral drugs that do not have the same active ingredients as they would have if given by injection. (ANSI X12 Group Code-PR 46)

80.2 - Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen

(Rev. 590, Issued: 06-24-05, Effective: 04-04-05, Implementation: 07-05-05)

See the Medicare Benefits Policy Manual, Chapter 15, for detailed coverage requirements.

Effective for dates of service on or after January 1, 1998, FIs and carriers pay for oral anti-emetic drugs when used as full therapeutic replacement for intravenous dosage forms as part of a cancer chemotherapeutic regimen when the drug(s) is administered or prescribed by a physician for use immediately before, at, or within 48 hours after the time of administration of the chemotherapeutic agent.

The allowable period of covered therapy includes day one, the date of service of the chemotherapy drug (beginning of the time of treatment), plus a period not to exceed two additional calendar days, or a maximum period up to 48 hours. Some drugs are limited to

24 hours; some to 48 hours. The hour limit is included in the narrative description of the HCPCS code.

The oral anti-emetic drug(s) should be prescribed only on a per chemotherapy treatment basis. For example, only enough of the oral anti-emetic(s) for one 24- or 48-hour dosage regimen (depending upon the drug) should be prescribed/supplied for each incidence of chemotherapy treatment. These drugs may be supplied by the physician in the office, by an inpatient or outpatient provider (e.g., hospital, CAH, SNF), or through a supplier (e.g., a pharmacy).

The physician must indicate on the prescription that the beneficiary is receiving the oral anti-emetic drug(s) as full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen. Where the drug is provided by a facility, the beneficiary's medical record maintained by the facility must be documented to reflect that the beneficiary is receiving the oral anti-emetic drug(s) as full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen.

Payment for these drugs is made under Part B. Beginning 1/1/05, the payment allowance limit for these Part B drugs (the term "drugs" includes biologicals) will be based on the Average Sales Price (ASP) plus 6%. Payment allowances for drugs will be based on the lower of the submitted charge or the ASP file price. These drugs continue to be priced based on the date of service. The drug payment allowance limit pricing file will be distributed to contractors by CMS. CMS will update and provide this file quarterly. Carriers/DMERCs/SADMERCs shall develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file.

The HCPCS codes shown in section 80.2.1 are used.

The CWF edits claims with these codes to assure that the beneficiary is receiving the oral anti-emetic(s) as part of a cancer chemotherapeutic regimen by requiring a diagnosis of cancer.

Most drugs furnished as an outpatient hospital service are packaged under OPPS. However, chemotherapeutic agents and the supportive and adjunctive drugs used with them are paid separately.

Effective for dates of service on or after April 4, 2005, coverage for the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT₃ antagonist, and dexamethasone is considered reasonable and necessary for only those patients who are receiving one or more of the following anti-cancer chemotherapeutic agents:

- Carmustine
- Cisplatin
- Cyclophosphamide
- Dacarbazine
- Mechlorethamine
- Streptozocin
- Doxorubicin

- Epirubicin
- Lomustine

80.2.1 - HCPCS Codes for Oral Anti-Emetic Drugs

(Rev. 590, Issued: 06-24-05, Effective: 04-04-05, Implementation: 07-05-05)

The physician/supplier bills for these drugs on Form CMS-1500 or its electronic equivalent. The facility bills for these drugs on Form CMS-1450 or its electronic equivalent. The following HCPCS codes are assigned:

- J8501 APREPITANT, 5mg, Oral (Code is Effective 1/1/05 but coverage is effective 4/4/05, Note: Aprepitant is only covered in combination with a 5-HT₃ antagonist, and dexamethasone for beneficiaries who have received one or more of the specified anti-cancer chemotherapeutic agents.
- Q0163 DIPHENHYDRAMINE HYDROCHLORIDE 50mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at time of chemotherapy treatment not to exceed a 48-hour dosage regimen.
- Q0164 PROCHLORPERAZINE MALEATE 5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0165 PROCHLORPERAZINE MALEATE 10mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0166 GRANISETRON HYDROCHLORIDE 1mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24-hour dosage regimen.
- Q0167 DRONABINOL 2.5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0168 DRONABINOL 5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0169 PROMETHAZINE HYDROCHLORIDE 12.5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0170 PROMETHAZINE HYDROCHLORIDE 25mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0171 CHLORPROMAZINE HYDROCHLORIDE 10mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV

anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

- Q0172 CHLORPROMAZINE HYDROCHLORIDE 25mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0173 TRIMETHOBENZAMIDE HYDROCHLORIDE 250mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0174 THIETHYLPERAZINE MALEATE 10mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0175 PERPHENAZINE 4mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0176 PERPHENAZINE 8mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hours dosage regimen.
- Q0177 HYDROXYZINE PAMOATE 25mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0178 HYDROXYZINE PAMOATE 50mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0179 ONDANSETRON HYDROCHLORIDE 8mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- Q0180 DOLASETRON MESYLATE 100mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24-hour dosage regimen.
- Q0181 UNSPECIFIED ORAL DOSAGE FORM, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

NOTE: The 24-hour maximum drug supply limitation on dispensing, for HCPCS Codes Q0166 and Q0180, has been established to bring the Medicare benefit as it applies to these two therapeutic entities in conformity with the “Indications and Usage” section of currently FDA-approved product labeling for each affected drug product.

80.2.2 - Claims Processing Jurisdiction for Oral Anti-Emetic Drugs

(Rev. 1, 10-01-03)

The table in §10 shows FI/carrier jurisdiction for oral anti-emetic drugs. Within this, the following chart shows which drugs are billed to the local carrier and which to the DMERC.

Per the BBA '97, effective for claims with dates of service on or after January 1, 1998, the claims processing jurisdiction rules in Chart 1 apply.

CHART 1

COMBINATION	JURISDICTION
Oral chemotherapy drug with oral anti-emetic drug	DMERC maintains processing responsibility for the NDC oral chemotherapy drug and the K0415 oral anti-emetic drug code combinations. DMERC processes the NDC oral chemotherapy drug and Q code oral anti-emetic drug(s) when provided in the physician's office. DMERC processes the NDC oral chemotherapy drug and/or Q code oral anti-emetic drug(s) when supplied by a pharmacy.
Oral chemotherapy drug with rectal anti-emetic drug	DMERC maintains responsibility for processing both the NDC oral chemotherapy drug and the K0416 rectal anti-emetic drug.
Oral chemotherapy drug with intravenous anti-emetic drug	DMERC maintains responsibility for processing the NDC oral chemotherapy drug and the local carrier for processing the intravenous anti-emetic J code drug(s).
Intravenous chemotherapy drug with oral anti-emetic drug	Local carrier processes the intravenous J code chemotherapy drug. The oral anti-emetic Q code drug(s) is processed by the DMERC when provided in the physician's office or when provided by a supplier.
Intravenous chemotherapy drug with intravenous anti-emetic drug	Local carrier processes both intravenous chemotherapy J code drug and intravenous anti-emetic J code drug(s).

Key: 1 = OBRA '93 Legislation (Coverage for Oral Anti-Cancer Drugs)

2 = Carrier Manual Transmittal No. 1528 (November 1995) (Adds oral/rectal anti-emetic)

3 = "Incident to" a physician service

For claims with dates of service prior to January 1, 1998, per OBRA '93, the claims processing jurisdiction rules in Chart 2 apply.

CHART 2

COMBINATION	UNDER OBRA '93
Oral chemotherapy drug with oral anti-emetic drug	DMERC processes both chemotherapy drug (NDC) [1] and the anti-emetic drug (K0415 code) [2].
Oral chemotherapy drug with rectal anti-emetic drug	DMERC processes both the chemotherapy drug (NDC) [1] and the anti-emetic drug (K0416 code) [2].
Oral chemotherapy drug with intravenous anti-emetic drug	DMERC processes the oral chemotherapy drug (NDC) [1] and the local carrier processes the intravenous anti-emetic drug (NDC) [3].
Intravenous chemotherapy drug with oral anti-emetic drug	Local carrier processes intravenous chemotherapy drug (NDC) [3] and self-administered oral anti-emetic drug is noncovered.
Intravenous chemotherapy drug with intravenous anti-emetic drug	Local carrier processes both intravenous chemotherapy drug (NDC) [3] and intravenous anti-emetic drug (NDC) [3].

Key: 1 = OBRA '93 Legislation (Coverage for Oral Anti-Cancer Drugs)

2 = Carrier Manual Transmittal No. 1528 (November 1995) (Adds oral/rectal anti-emetic)

3 = "Incident to" a physician service

Providers (HIPAA definition) that bill the DMERC require a supplier number issued by the NSC in order to submit claims. Medicare Part B carriers should instruct providers without a supplier number to contact the NSC service center at 803-754-3951 to request an enrollment package for a supplier number.

80.2.3 - MSN /ANSI X12N Denial Messages for Anti-Emetic Drugs

(Rev. 684, Issued: 09-23-05; Effective and Implementation Dates: 12-23-05)

If the claim for an anti-emetic drug is denied because FDA did not approve it or because the drug is not being used as part of an anticancer chemotherapeutic regimen, the contractor uses one of the following appropriate messages on the MSN:

6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered. (ANSI X12 Adjustment Code 114)

6.4 - Medicare does not pay for an oral anti-emetic drug that is not administered for use immediately before, at, or within 48 hours after administration of a Medicare covered chemotherapy drug. (ANSI X12 Group Code PR 96 with Remark Code M100)

80.2.4 - Billing and Payment Instructions for FIs

(Rev. 590, Issued: 06-24-05, Effective: 04-04-05, Implementation: 07-05-05)

Claims for oral anti-emetic drug aprepitant must be billed to the FI on Form CMS-1450 (UB-92) or the electronic equivalent with the appropriate cancer diagnosis and HCPCS code or CPT code. The following payment methodologies apply when furnished to hospital and SNF outpatients:

- Based on APC for hospitals subject to OPPS;
- Under current payment methodologies for hospitals not subject to OPPS; or
- On a reasonable cost basis for SNFs.

Institutional providers bill for aprepitant under Revenue Code 0636 (Drugs requiring detailed coding).

Medicare contractors shall pay claims submitted for services provided by a CAH as follows: Method I technical services are paid at 101% of reasonable cost; Method II technical services are paid at 101% of reasonable cost, and, Professional services are paid at 115% of the Medicare Physician Fee Schedule Data Base.

NOTE: Inpatient claims submitted for oral anti-emetic drugs are processed under the current payment methodologies.

80.3 - Billing for Immunosuppressive Drugs

(Rev. 1, 10-01-03)

B3-4471, A3-3660.8, PM AB-01-10

Beginning January 1, 1987, Medicare pays for FDA approved immunosuppressive drugs and for drugs used in immunosuppressive therapy. (See the Medicare Benefit Policy Manual, Chapter 15 for detailed coverage requirements.) Generally, contractors pay for self-administered immunosuppressive drugs that are specifically labeled and approved for marketing as such by the FDA, or identified in FDA-approved labeling for use in conjunction with immunosuppressive drug therapy. This benefit is subject to the Part B deductible and coinsurance provision.

Contractors are expected to keep informed of FDA additions to the list of the immunosuppressive drugs and notify providers. Prescriptions for immunosuppressive drugs generally should be nonrefillable and limited to a 30-day supply. The 30-day guideline is necessary because dosage frequently diminishes over a period of time, and further, it is not uncommon for the physician to change the prescription from one drug to another. Also, these drugs are expensive and the coinsurance liability on unused drugs could be a financial burden to the beneficiary. Unless there are special circumstances, contractors will not consider a supply of drugs in excess of 30 days to be reasonable and necessary and should deny payment accordingly.

Entities that normally bill the carrier bill the DMERC. Entities that normally bill the FI continue to bill the FI, except for hospitals subject to OPPS, which must bill the DMERC.

Prior to December 21, 2000 coverage was limited to immunosuppressive drugs received within 36 months of a transplant. ESRD beneficiaries continue to be limited to 36

months of coverage after a Medicare covered kidney transplant. For all other beneficiaries, BBA '97 increased the length of time a beneficiary could receive immunosuppressives by a sliding method. So for the period 8/97 thru 12/00 a longer period of time MAY apply for a transplant. Effective with immunosuppressive drugs furnished on or after December 21, 2000, there is no time limit, but an organ transplant must have occurred for which immunosuppressive therapy is appropriate. That is, the time limit for immunosuppressive drugs was eliminated for transplant beneficiaries that will continue Medicare coverage after 36 months based on disability or age. The date of transplant is reported to the FI with occurrence code 36.

CWF will edit claim records to determine if a history of a transplant is on record. If not an error will be returned. See Chapter 27 for edit codes and resolution.

80.3.1 - Requirements for Billing FI for Immunosuppressive Drugs

(Rev. 1, 10-01-03)

Hospitals not subject to OPPS bill on a Form CMS-1450 with bill type 12x (hospital inpatient Part B) or 13x (hospital outpatient) as appropriate. For claims with dates of service prior to April 1, 2000, providers report the following entries:

- Occurrence code 36 and date in FL 32-35;
- Revenue code 0250 in FL 42; and
- Narrative description in FL 43.

For claims with dates of service on or after April 1, 2000, hospitals report

- Occurrence code 36 and date in FL 32-35;
- Revenue code 0636 in FL 42;
- HCPCS code of the immunosuppressive drug in FL 44; and
- Number of units in FL 46 (the number of units billed must accurately reflect the definition of one unit of service in each code narrative. E.g.: If fifty 10-mg. Prednisone tablets are dispensed, the hospital bills J7506, 100 units (1 unit of J7506 = 5 mg.).

The hospital completes the remaining items in accordance with regular billing instructions.

80.3.2 - MSN/Remittance Messages for Immunosuppressive Drugs

(Rev. 1, 10-01-03)

A. MSN

MSN messages for denied Immunosuppressive Drugs are as follows:

If no transplant use:

- 6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered.

If the claim for an immunosuppressive drug is partially denied because of the 30-day supply limitation, use the following message:

4.3 - Prescriptions for immunosuppressive drugs are limited to a 30-day supply.

B. Remittance

Remittance codes/messages for denied Immunosuppressive Drugs are as follows:

If the claim is denied because the immunosuppressive drug is not approved by the FDA, the FI uses existing American National Standard Institute (ANSI) X-12-835 claim adjustment reason code/message 114, Procedure/product not approved by the Food and Drug Administration.

If the claim is denied because the benefit period has expired or because of the 30 day limitation, the FI uses existing ANSI X12N 835 claim adjustment reason code/message 35, Benefit maximum has been reached.

If the claim is denied for the immunosuppressive drug because a transplant was not covered, the FI uses existing ANSI X12N 835 claim adjustment reason code/message 107, Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

80.4 - Billing for Hemophilia Clotting Factors

(Rev. 521, Issued: 04-08-05; Effective/Implementation Dates: 05-09-05)

Blood clotting factors not paid on a cost or prospective payment system basis are priced as a drug/biological under the drug pricing fee schedule effective for the specific date of service. As of January 1, 2005, the average sales price (ASP) plus 6 percent shall be used.

If a beneficiary is in a covered part A stay in a PPS hospital, the clotting factors are paid in addition to the DRG/HIPPS payment (For FY 2005, this payment is based on 95 percent of AWP). For a SNF subject to SNF/PPS, the payment is bundled into the SNF/PPS rate.

For hospitals subject to OPPS, the clotting factors, when paid under Part B, are paid the APC. For SNFs the clotting factors, when paid under Part B, are paid based on cost.

Local carriers shall process non-institutional blood clotting factor claims.

The FIs shall process institutional blood clotting factor claims (Part A and Part B institutional).

80.5 - Self-Administered Drugs

(Rev. 1, 10-01-03)

A3-3660.11, A3-3660.12, SNF-536.1, AB-02-72

See the Medicare Benefit Policy Manual, chapter 15-1.

A. Reporting Requirement

Each carrier and FI must report to CMS every September 1 and April 1 (i.e., every 6 months) its complete list of injectable drugs that are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered by the patient.

Contractors must E-mail this list along with the contractor's name, Medicare identification number and the State(s) affected by the list to: drugdata@cms.hhs.gov.

80.6 – Intravenous Immune Globulin

(Rev. 74, 01-23-04)

Beginning for dates of service on or after January 1, 2004, Medicare pays for intravenous immune globulin administered in the home. (See the Medicare Benefit Policy Manual, Chapter 15 for coverage requirements.) Contractors pay for the drug, but not the items or services related to the administration of the drug when administered in the home, if deemed medically appropriate.

Contractors may pay any entity licensed in the State to furnish intravenous immune globulin. Payment will be furnished to the entity with the authority to furnish the drug. Beneficiaries are ineligible to receive payment for the drug.

Pharmacies and hospitals dispensing intravenous immune globulin would bill the DMERC. Home Health Agencies dispensing intravenous immune globulin would bill the RHHI. Physicians furnishing intravenous immune globulin for the refilling of an external pump for home infusion would bill the DMERC.

The appropriate ICD-9 codes are as follows: 279.04, 279.05, 279.06, 279.12, and 279.2. The appropriate HCPCs codes are J1563 and J1564.

80.7 - Pharmacy Supplying Fee and Inhalation Drug Dispensing Fee

(Rev.754, Issued: 11-10-05, Effective: 01-01-06, Implementation: 01-03-06)

Section 303(e) (2) of the MMA implements a supplying fee for immunosuppressive drugs, oral anti-cancer chemotherapeutic drugs, and oral anti-emetic drugs used as part of an anti-cancer chemotherapeutic regimen. Effective January 1, 2005, Medicare paid a separately billable supplying fee of \$24.00 to a pharmacy, dialysis facility in the State of Washington or any hospital outpatient department not subject to the OPDS for each supplied prescription of the above-mentioned drugs. In addition, Medicare also paid a separately billable supplying fee of \$50.00 for the initial supplied prescription of the immunosuppressive drugs during the first month following the patient's transplant.

Effective January 1, 2006, we are changing the supplying fee when multiple prescriptions are supplied in a 30-day period. Medicare will pay \$24 for the first prescription of the above-mentioned drugs supplied by a pharmacy in a 30-day period, and will pay \$16 for each subsequent prescription, after the first one, supplied in that 30-day period. A pharmacy will be limited to one \$24 fee per 30-day period even if the pharmacy supplies more than one category of the abovementioned drugs (for example, an oral-anticancer drug and an oral anti-emetic drug) to a beneficiary. If two different pharmacies supply the above-mentioned drugs to a beneficiary during a 30-day period, each pharmacy will be eligible for one \$24 supplying fee for the first prescription supplied during that 30-day period, and a supplying fee of \$16 for each subsequent prescription supplied in that 30-day period. For a refill prescription, Medicare will allow payment of a \$24 supplying fee to a particular supplier up to seven days before the end of the 30-day period for which the last \$24 supplying fee was paid to that supplier; however, each supplier will be limited to twelve \$24 supplying fees per beneficiary per year. Medicare will pay a supplying fee

for each prescription, including prescriptions for different strengths of the same drug supplied on the same day (for example, a prescription for 100 mg tablets and 5 mg Tablets). These changes do not alter the one-time \$50 supplying fee for the first immunosuppressive prescription after a transplant.

We are also changing the dispensing fee for inhalation drugs furnished through durable medical equipment. Effective January 1, 2006, Medicare will pay an initial dispensing fee of \$57 to a pharmacy for the initial 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This initial 30-day dispensing fee is a one-time fee applicable only to beneficiaries who are using inhalation drugs for the first time as a Medicare beneficiary. Except in those circumstances where an initial 30-day dispensing fee is applicable, Medicare will pay a dispensing fee of \$33 to a pharmacy/supplier for each 30-day supply of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during the 30 day period. Medicare will pay a dispensing fee of \$66 to a pharmacy/supplier for each 90-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during the 90 days. Only one 30-day dispensing fee will be payable per 30-day period, and only one 90-day dispensing fee will be payable per 90-day period, regardless of the numbers of suppliers used during the respective periods. A 30-day and 90-day supplying fee cannot be paid for drug supplied for the same month. For a refill prescription, Medicare will allow payment of the dispensing fee no sooner than 7 days before the end of usage for the current 30-day or 90-day period for which a dispensing fee was previously paid. Each inhalation drug supplier will be allowed no more than 12 months of dispensing fees per beneficiary per year. Medicare will not pay separately for compounding drugs. This cost is in the dispensing fees.

Supply fees and dispensing fees must be billed on the same claim as the drug.

HCPCS Codes and Fees:

GO369, G0370, G0371, G0374 – not recognized by Medicare as of 1/1/06.

Q0510 – First immunosuppressive prescription after a transplant, \$50.00 fee

Q0511 – Pharmacy supplying fee for immunosuppressive, oral-anti-cancer, and oral anti-emetic drugs, first prescription in a one month period. Each pharmacy may receive this fee once in a 30-day period. Fee is \$24.00

Q0512 – Pharmacy supplying fee for immunosuppressive, oral anti-cancer, and oral anti-emetic drugs – each subsequent prescription in a 30-day period. Fee is \$16.00.

Q0513 – Pharmacy dispensing fee for inhalation drug(s); per 30-days.

Effective 1/1/06, Medicare will pay a dispensing fee of \$33.00 to a pharmacy for a 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that period. Payment will be made on the first claim received.

Q0514 – Pharmacy dispensing fee for inhalation drugs(s); per 90-days.

Effective 1/1/06, Medicare will pay a dispensing fee of \$66.00 to a pharmacy for a 90-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that period. Payment will be made on the first claim received.

G0333- Pharmacy dispensing fee for initial inhalation drug(s); initial 30 day supply to a beneficiary.

Effective January 1, 2006, Medicare will pay an initial dispensing fee of \$57.00 to a pharmacy for the initial 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This initial 30-day dispensing fee is a one-time fee applicable only to beneficiaries who are using inhalation drugs for the first time as a Medicare beneficiary.

Based on the code descriptions above, a supplying fee and a dispensing fee is not appropriate for one drug. The supplying fee is for immunosuppressives, oral anti-cancer drugs and oral anti-emetic drugs. The dispensing fee is for inhalation drugs only. A supplier cannot be paid for more than one of the following -- an initial dispensing fee (G0333), a 30-day dispensing fee (Q0513), or a 90-day dispensing fee (Q0514) – for a beneficiary for the same period.

80.9 - Hospitals Billing for Epoetin Alfa (EPO) for Non-ESRD Patients

(Rev. 736, Issued: 10-31-05; Effective Date: 01-01-06; Implementation Date: 04-03-06)

NOTE: For EPO billing instructions for beneficiaries with ESRD, see the Claims Processing Manual, Chapter 8.

For patients with chronic renal failure who are not yet on a regular course of dialysis, EPO administered in a hospital and billed as an outpatient service on type of bill 13x or inpatient Part B bill type 12x are paid under the Outpatient Prospective Payment System (OPPS). Non-OPPS hospitals are paid on reasonable charges.

Hospitals report charges under revenue code 0636 with HCPCS code Q0136 (replaced with J0885 effective January 1, 2006). Value codes 48, 49, and 68 and condition codes 70 through 76 should not be used when billing for EPO administered to non-ESRD patients.

80.10 - Hospitals Billing for Darbepoetin Alfa (Aranesp) for Non-ESRD Patients

(Rev. 736, Issued: 10-31-05; Effective Date: 01-01-06; Implementation Date: 04-03-06)

NOTE: For Aranesp billing instructions for beneficiaries with ESRD, see the Claims Processing Manual, Chapter 8.

For patients with chronic renal failure who are not yet on a regular course of dialysis, Aranesp administered in a hospital and billed as an outpatient service on type of bill 13x or inpatient Part B bill type 12x are paid under the Outpatient Prospective Payment System (OPPS). Non-OPPS hospitals are paid on reasonable charges.

Hospitals report charges under revenue code 0636 with HCPCS code Q0137 (replaced with J0881 effective January 1, 2006). Value codes 48, 49 and 68 and condition codes 70 through 76 should not be used when billing for EPO administered to non-ESRD patients.

90 - Claims Processing Rules for Hospital Outpatient Billing and Payment

(Rev. 1, 10-01-03)

90.1 - Blood/Blood Products and Drugs Classified in Separate APCs for Hospital Outpatients

(Rev. 496, Issued: 03-04-05, Effective: 07-01-05, Implementation: 07-05-05)

Proper Billing for Blood Products and Blood Storage and Processing

Refer to Pub.100-04, Medicare Claims Processing Manual, Chapter 4, §231 regarding billing for blood and blood products under the Hospital Outpatient Prospective Payment System (OPPS).



2 - Changes to Pass-Through Drugs and Biologicals Final Rule

(Rev. 1, 10-01-03)

PM A-02-026

The CMS updates the payment rates for pass-through drugs and biologicals annually and provides notification of the changes. The all-inclusive list of billable drugs for pass-through payment is included in the current regulation. The most current regulation can be found under the CMS quarterly provider updates on the CMS Web site at:



www.hhs.gov/providerupdate/regsum.asp#1206fc.

90.2.1 - HCPCS Codes Replacements

(Rev. 1, 10-01-03)

PM A-02-026 §IX.A

The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPPS is published quarterly via Program Memorandum. The latest payment rates associated with each APC number may be found in the OPPS PRICER file available on the CMS Web site, as well as in Addendum A and B of OPPS Final Rule. Refer to the current rule found at <http://www.cms.hhs.gov/providerupdate/regs/cms1206cn2.pdf>.

90.2.2 - Codes Not Recognized for Medicare Under the Hospital OPPS

(Rev. 1, 10-01-03)

PM A-02-026 §IX.B

Effective April 1, 2002, the following HCPCS codes are no longer recognized under the hospital OPPS. These codes were either assigned to a status indicator of “D” or “E” in

the OPPTS Final Rule that was published on March 1, 2002. Refer to current rule found at <http://www.cms.hhs.gov/providerupdate/regs/cms1206cn2.pdf>.

NOTE: These codes, if reported, must be taken in on the claim, along with codes recognized by Medicare, and crossed over to a secondary or supplementary payor.

HCPCS Code	APC	Short Descriptor	Additional Information
C1090	1090	IN 111 chloride, per mCi	Based on consultation with a nuclear pharmaceutical expert, We determined that this radiopharmaceutical agent is never administered in isolation. It is always combined with another agent. Therefore, this code will no longer be reportable under the hospital OPPTS.
J1810	7047	Droperidol/fentanyl inj	Review of this specific drug indicates that it is no longer manufactured. Therefore, this code will no longer be reportable under the hospital OPPTS.
J9266	843	Pegaspargase/singl dose vial	Review of this specific drug indicates that it is no longer manufactured. Therefore, this code will no longer be reportable under the hospital OPPTS.
Q2020	1616	Histrelin acetate	Review of this specific drug indicates that it is no longer manufactured. Therefore, this code will no longer be reportable under the hospital OPPTS.

90.2.3 - Additional Drugs Eligible for Pass-Through Payments

(Rev. 1, 10-01-03)

PM A-02-026 §IX.C

Additional drugs are eligible for pass-through payments. Refer to the most current rule found at: <http://www.cms.hhs.gov/providerupdate/regs/cms1206cn2.pdf>.

90.2.4 - Changes to Payment Rates and Co-Pay From the March 1, 2002 OPPTS Final Rule

(Rev. 1, 10-01-03)

PM A-02-026 §IX.D

The information below supercedes what was published in the March 1, 2002 Final Rule, and was updated in OPPTS PRICER effective April 1, 2002. Only applicable changes are noted below.

HCPCS	APC	Short Descriptor	Old Payment Rate	Old Co-Pay	Corrected Payment Rate	Corrected Co-Pay
C9010	9010	Baclofen refill kit - per 4000 mcg	\$ 43.08	\$ 6.17	\$ 86.17	\$ 12.34
J1190	726	Dexrazoxane HCL injection per 250 mg	N/A	24.98	N/A	27.85
J1327	1607	Eptifibatide injection, 5 mg	N/A	1.45	N/A	1.62
J7330	1059	Cultured chondrocytes implnt	14,250.00	2040.00	14,250.00	2,040.00
J7505	7038	Monoclonal antibodies	269.06	38.52	777.31	111.28
Q3007	1624	Sodium phosphate p32	N/A	7.78	N/A	11.61

90.2.5 - Additional Corrections

(Rev. 1, 10-01-03)

PM A-02-026 §IX.E

The information below identifies additional information or changes to the November 30, 2001, and/or March 1, 2002, Final Rule. These changes are effective April 1, 2002.

HCPCS

Code	APC	SI	Short Descriptor	Additional Information
A4642	0704	G	Satumomab pendetide, per dose	Status Indicator changed to "E"
J1561	0905	G	Immune globulin 500 mg	To be used instead of HCPC J1563
Q0081	0120	T	Infusion ther other than che	Still a valid code, not discontinued

90.2.6 - Additional Billing and Reporting Information Related to Pass-Through Drugs Effective April 1, 2002

(Rev. 1, 10-01-03)

PM A-02-026 §IX.F

Below is additional information for the HCPCS codes listed in the November 30, 2001, and/or March 1, 2002 Final Rule.

HCPCS Code	APC	Short Descriptor	Additional Information
A9504	1602	Technetium tc 99m apcitide [per vial]	Payment rate for this radiopharmaceutical is based on "per vial."
C1064	1064	I-131 cap , each add mCi	<p>This code should be reported after the first initial 1-5 mCi. This dosage is to be used for 6 or more capsules and is used in conjunction with C1188. For example, for a patient that received 7 mCi of I-131 capsules, the following codes should be reported:</p> <p>C1188 initial 1-5 mCi Units of service: 1 C1064 each add'l mCi Units of service: 2</p>
C1065	1065	I-131 sol , each add mCi	<p>This code should be reported after the first initial 1-6 mCi. For example, for a patient that received 7 mCi of I-131 solution, the following codes should be reported:</p> <p>C1348 initial 1-6 mCi Units of service: 1 C1065 each add'l mCi Units of service: 2</p>
C1066	1066	In 111 Satumomab pentetide	Under OPPS, A4642 will no longer be reportable effective 04/01/2002. This radiopharmaceutical has been replaced with C1066.
C1188	1188	I-131 cap , per 1-5 mCi	This code should be reported for only the initial 1-5 mCi dose of I-131 capsules.
C1305	1305	Apligraf	Only HCPCS code C1305 is reportable under the hospital OPPS. HCPCS J7340 should NOT be reported for Apligraf under the hospital OPPS.
C1348	1348	I-131 sol , per 1-6 mCi	This code should be reported for only the initial 1-6 mCi dose of I-131 solution.
C9003	9003	Palivizumab, per 50 mg	The payment rate for this drug was based on a pediatric dose.
C9019	9019	Caspofungin acetate, 5 mg	<p>Dosage Descriptor Alert:</p> <p>The dosage for this code has been changed from 50 mg to 5 mg</p>
C9020	9020	Sirolimus solution, 1 mg	<p>Dosage Descriptor Alert:</p> <p>The descriptor for this code has been changed from</p>

HCPCS

Code	APC	Short Descriptor	Additional Information
			Sirolimus tablet, 1 mg to Sirolimus solution 1 mg.
J1565	906	RSV-ivig	The payment rate for this drug was based on a pediatric dose.
Q2008	7027	Fomepizole, 15 mg	Dosage Descriptor Alert: The dosage for this code has been changed from 1.5 mg to 15 mg.

90.2.7 - Typographical Errors from the March 1, 2002, OPPS Final Rule**(Rev. 1, 10-01-03)****PM A-02-026 §IX.G**

The dosage descriptors and short descriptors for the following HCPCS codes were incorrectly listed in Addendum A and B of the March 1, 2002, Final Rule. The information below corrects the information published in the Final Rule.

HCPCS

Code	APC	March 1, 2002 Final Rule	Corrected Information
C1079	1079	Addendum A CO 57/58 0.5 mCi	Co 57/58 0.5 uCi
C1094	1094	Addendum A TC 99M Albumin aggr, 1.0 cmCi	TC 99M albumin aggr, 1.0 mCi
C9110	9110	Addendum A Alemtuzumab, per ml	Alemtuzumab, per 10mg/ml
J1626	764	Addendum A Granisetron hcl injection 10 mcg	Granisetron HCL injection 100 mcg
Q0187	1409	Addendum A and B Factor VIII recombinant, per 1.2 mg	Factor viia recombinant
Q3004	1621	Addendum A Xenin xe 133	Xenon xe 133

90.2.8 - Correction to 2003 HCPCS Code Books

(Rev. 1, 10-01-03)

PM A-02-026 §IX.H

The 2003 Level II HCPCS Code Books contained the following errors in transcription for drugs, biologicals and radiopharmaceuticals. Please ensure that providers are aware of these errors and that units of service on claims should reflect the **CORRECT** descriptor dosages.

NOTE: The MCI or mCi is standard abbreviation for millicurie; uCi is standard abbreviation for microcurie.

For the latest 2003 Level II HCPCS short and long descriptors, refer to the 2003 HCPCS file which can be downloaded from the CMS Web site at:

<http://cms.hhs.gov/providers/pufdownload/default.asp#alphanu>.

Code	Name	Publication Dose	Correct Dose
A9503	Technetium TC 99m medronate	up to 30 microcurie	up to 30 MCI
A9504	Technetium TC 99m apcitide	none noted	per vial
A9505	Thallous chloride TL-201/mci	per microcurie	per MCI
A9508	Iobenguane sulfate I-131 per 0.5 mci	per 0.5 microcurie	per 0.5 MCI
A9511	Technetium Tc 99m depreotide	per microcurie	per MCI
A9600	Strontium-89 chloride per mCi	per microcurie	per MCI
A9605	Samarium sm 153 lexidronanim 50 mCi	per 50 microcurie	per 50 MCI
C1064	I-131 cap, each add mCi	each additional microcurie	each additional MCI (6+ MCI)
C1065	I-131 sol, each add mCi	each additional microcurie	each additional MCI (7+ MCI)
C1188	I-131 cap, per 1-5 mCi	per initial 1-5 microcurie	per initial 1-5 MCI
C1348	I-131 sol, per 1-6 mCi	per initial 1-6 microcurie	per initial 1-6 MCI
C9000	Na chromatecr51, per 0.25mCi	per 0.25	per 0.25 MCI

Code	Name	Publication Dose microcurie	Correct Dose
C9013	Co 57 cobaltous chloride	no dose	per 10 uCi
C9100	Iodinated I-131 Albumin	per microcurie	per MCI
C9102	51 Na Chromate, 50mCi	per 50 microcurie	per 50 MCI
Q2008	Fomepizole, 15mg	1.5 mg	15 mg
Q3002	Gallium ga 67, per mCi	per microcurie	per MCI
Q3004	Xenon xe 133	per 10 microcuries	per 10 MCI
Q3005	Technetium tc 99m mertiotide	per microcurie	per MCI
Q3006	Technetium tc 99m gluceptate	per 5 microcurie	per 5 MCI
Q3007	Sodium phosphate P32	per microcurie	per MCI
Q3008	Indium 111-in pentetretotide	per 3 microcurie	per 3 MCI
Q3009	Technetium tc99m oxidronate	per microcurie	per MCI
Q3010	Technetium tc99mlabeledrbcs	per microcurie	per MCI
Q3011	Chromic phosphate p32	per microcurie	per MCI
Q3012	Co 57, 0.5 Mci	per 0.5 microcurie	per 0.5 MCI

90.2.9 - Pro-Rata Reduction in Drug and Device Pass-Through Payments

(Rev. 1, 10-01-03)

PM A-02-026 §X

The final rule published in the “Federal Register” on March 1, 2002, announced a uniform reduction of 63.6 percent to be applied to each of the transitional pass-through payments for drug and devices furnished on or after April 1, 2002. See the “Federal Registers” published on November 1, 2001, November 30, 2001, and March 1, 2002 for a full discussion of these reductions. The reductions were implemented in the OPPS PRICER program for drugs and devices furnished on or after April 1, 2002.

Table 1, as published in the March 1, 2002 “Federal Register,” lists the device offset amounts attributable to APCs. These amounts are used in calculating device payments that reflect the pro-rata reduction as illustrated in the example that follows.

Table 1 - Offsets to Be Applied for Each APC That Contains Device Costs

APC	Description	Device Costs (Before Fold-in) Reflected in APC Rate	Additional Device Costs Folded into APC Rate	Total Offset for Device Costs
0032	Insertion of Central Venous/Arterial Catheter	\$73.79	\$279.97	\$353.76
0046	Open/Percutaneous Treatment Fracture or Dislocation	NA	\$100.29	\$100.29
0048	Arthroplasty with Prosthesis	NA	\$514.64	\$514.64
0057	Bunion Procedures	NA	\$162.89	\$162.89
0070	Thoracentesis/Lavage Procedures	NA	\$26.47	\$26.47
0080	Diagnostic Cardiac Catheterization	\$164.27	\$134.39	\$298.66
0081	Non-Coronary Angioplasty or Atherectomy	\$307.06	\$362.95	\$670.01
0082	Coronary Atherectomy	\$242.95	\$1,214.06	\$1,457.01
0083	Coronary Angioplasty	\$528.64	\$383.31	\$911.95
0085	Level II Electrophysiologic Evaluation	NA	\$1,578.03	\$1,578.03
0086	Ablate Heart Dysrhythm Focus	NA	\$1,320.96	\$1,320.96
0087	Cardiac Electrophysiologic Recording/Mapping	NA	\$1,980.16	\$1,980.16
0088	Thrombectomy	\$162.72	\$261.14	\$423.86
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	\$3,175.70	\$3,286.36	\$6462.06
0090	Insertion/Replacement of Pacemaker Pulse Generator	\$2,921.06	\$2,123.20	\$5,044.26
0094	Resuscitation and Cardioversion	NA	\$19.34	\$19.34

APC	Description	Device Costs (Before Fold-in) Reflected in APC Rate	Additional Device Costs Folded into APC Rate	Total Offset for Device Costs
0103	Miscellaneous Vascular Procedures	NA	\$207.18	\$207.18
0104	Transcatheter Placement of Intracoronary Stents	\$428.16	\$1,256.31	\$1,684.47
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	\$657.59	\$1,049.13	\$1,706.72
0107	Insertion of Cardioverter-Defibrillator	\$6,803.85	\$11,099.62	\$17,903.47
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	\$6,940.27	\$19,607.20	\$26,547.47
0111	Blood Product Exchange	NA	\$209.72	\$209.72
0115	Cannula/Access Device Procedures	NA	\$127.26	\$127.26
0117	Chemotherapy Administration by Infusion Only	NA	\$30.03	\$30.03
0118	Chemotherapy Administration by Both Infusion and Other Technique	NA	\$28.50	\$28.50
0119	Implantation of Devices	NA	\$3,348.98	\$3,348.98
0120	Infusion Therapy Except Chemotherapy	NA	\$35.12	\$35.12
0121	Level I Tube Changes and Repositioning	NA	\$6.10	\$6.10
0122	Level II Tube Changes and Repositioning	\$72.55	\$214.82	\$287.37
0124	Revision of Implanted Infusion Pump	NA	\$3,308.76	\$3,308.76
0144	Diagnostic Anoscopy	NA	\$128.28	\$128.28

APC	Description	Device Costs (Before Fold-in) Reflected in APC Rate	Additional Device Costs Folded into APC Rate	Total Offset for Device Costs
0151	Endoscopic Retrograde Cholangio-Pancreatography (ERCP)	\$60.92	\$0.00	\$60.92
0152	Percutaneous Biliary Endoscopic Procedures	\$107.61	\$0.00	\$107.61
0153	Peritoneal and Abdominal Procedures	NA	\$41.23	\$41.23
0154	Hernia/Hydrocele Procedures	\$108.11	\$378.73	\$486.84
0161	Level II Cystourethroscopy and other Genitourinary Procedures	NA	\$11.20	\$11.20
0162	Level III Cystourethroscopy and other Genitourinary Procedures	NA	\$319.68	\$319.68
0163	Level IV Cystourethroscopy and other Genitourinary Procedures	NA	\$901.51	\$901.51
0179	Urinary Incontinence Procedures	NA	\$3,400.90	\$3,400.90
0182	Insertion of Penile Prosthesis	\$2,238.90	\$569.11	\$2,808.14
0202	Level VIII Female Reproductive Proc	\$505.32	\$1,233.41	\$1,738.73
0203	Level V Nerve Injections	NA	\$420.98	\$420.98
0207	Level IV Nerve Injections	NA	\$63.63	\$63.63
0222	Implantation of Neurological Device	\$4,458.57	\$9,599.99	\$14,058.56
0223	Implantation of Pain Management Device	\$421.33	\$3,330.14	\$3,751.47
0225	Implantation of Neurostimulator Electrodes	\$1,182.00	\$11,941.06	\$13,123.06

APC	Description	Device Costs (Before Fold-in) Reflected in APC Rate	Additional Device Costs Folded into APC Rate	Total Offset for Device Costs
0226	Implantation of Drug Infusion Reservoir	NA	\$3,363.74	\$3,363.74
0227	Implantation of Drug Infusion Device	\$3,810.46	\$2,395.55	\$6,206.01
0229	Transcatherter Placement of Intravascular Shunts	\$1,074.41	\$842.97	\$1,917.38
0246	Cataract Procedures with IOL Insert	\$146.82	\$0.00	\$146.82
0259	Level VI ENT Procedures	\$12,407.52	\$3,836.13	\$16,243.65
0264	Level II Miscellaneous Radiology Procedures	NA	\$61.59	\$61.59
0312	Radioelement Applications	NA	\$5,897.22	\$5,897.22
0313	Brachytherapy	NA	\$998.23	\$998.23
0685	Level III Needle Biopsy/Aspiration Except Bone Marrow	NA	\$210.75	\$210.75
0686	Level V Skin Repair	NA	\$465.77	\$465.77
0687	Revision/Removal of Neurostimulator Electrodes	NA	\$1,444.65	\$1,444.65
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver	NA	\$6,238.79	\$6,238.79
0692	Electronic Analysis of Neurostimulator Pulse Generators	NA	\$644.44	\$644.44

The following examples illustrate how transitional pass-through payments are calculated for devices and for drugs, taking into account the pro-rata reductions.

**A. Example of Transitional Pass-Through Calculation for a Pass-Through Device
Furnished On or After April 1, 2002**

Device: C1776 Joint device (implantable)

Device cost = Hospital charge converted to cost = \$960

Associated procedure: CPT 25446 Wrist replacement (APC 48)

Payment rate = \$2211.27

National unadjusted copayment amount = \$725.94

Total offset amount to be applied for each APC that contains device costs = \$514.64

[**Note:** the total offset amount (from Table 1 above) is wage and discount factor adjusted before it is subtracted from the device cost.]

Device cost adjusted by total offset amount: $\$960 - \$514.64 = \$445.36$

Device cost after adjustment for pro rata reduction: $\$445.36 \times .364 = \162.11

Medicare program payment (before wage index adjustment) for APC 48: $\$2211.27 - 725.94 = \1485.33

Medicare program payment for pass-through device C1776 = \$162.11

Beneficiary copayment liability: \$725.94

Total amount received by provider for APC 48 and pass-through device C1776

\$1485.33 (Medicare program payment for CPT code 25446)

725.94 (Beneficiary unadjusted copayment amount for CPT code 25446)

162.11 (Transitional pass-through payment for device)

\$2373.38

B. Example of Transitional Pass-Through Calculation for a Pass-Through Drug Furnished On or After April 1, 2002

APC 1613 Trastuzumab, 10 mg

Unadjusted Copayment Amount = \$7.56

Payment rate = \$52.83

Non-pass-through portion = (5 x copay) = $5 \times 7.56 = \$37.80$

Pass-through portion = $\$52.83 - \$37.80 = \$15.03$

Pass-through portion after adjustment for 63.6 percent pro rata reduction

$\$15.03 \times .364 = \5.47

Total payment to provider for APC 1613 after pro rata reduction:

\$5.47 (pass-through portion adjusted for pro rata reduction)

37.80 (non-pass-through portion)

\$43.27 (total payment to provider)

- 7.56 (beneficiary copayment)

\$35.71 (total Medicare program payment)

90.3 – Hospital Outpatient Payment Under OPPTS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code

(Rev. 188, 05-28-04)

Section 621(a) of the MMA amends Section 1833(t) of the Social Security Act by adding paragraph (15), Payment for New Drugs and Biologicals Until HCPCS Code Assigned. Under this provision, payment for an outpatient drug or biological that is furnished as part of covered outpatient department services for which a product-specific HCPCS code has not been assigned shall be paid an amount equal to 95 percent of average wholesale price (AWP). This provision applies only to payments under the hospital outpatient prospective payment system (OPPS).

Beginning January 1, 2004, hospital outpatient departments may bill for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which pass-through status has not been approved and a C-code and APC payment have not been assigned.